

REMARKS

Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 67 and 69-77 now remain in the application. Claims 29, 33, 61, 62 and 63 were amended. Claim 68 has been cancelled.

The Office Action (final) contained 35 U.S.C. § 112 rejections alleging indefiniteness and lack of antecedent failings. It additionally contained 35 U.S.C. § 103(a) rejections based on Chopra in view of Motoyama et al. Finally, it contained provisional, obviousness-type double patenting rejections. In view of the foregoing amendments and arguments hereinafter set forth, it is respectfully submitted that those rejections should be withdrawn.

With regard to the 35 U.S.C. § 112, second paragraph rejections, "fat and oil" is a well-known generic term for a group of compounds (containing both solid and liquid compounds at a room temperature) in which a glycerin is esterified in claim 62 and on page 22, line 31 – page 23, line 13, etc. in the specification. One skilled in the art readily understands the meaning of the term "fat and oil", a term which in English usage has the same meaning as the term "oil and fat". In the context of this discussion, the phrase, "when the fat and oil and the polyol exist together" is added in claim 63. As such, claim 63 serves to clarify the meaning(s).

With regard to 35 the U.S.C. § 103(a) rejections, the present inventions (after amendment) relates to a reduced coenzyme Q₁₀-containing composition which comprises reduced coenzyme Q₁₀, a polyglycerol fatty acid ester, and a fat and oil and/or a polyol, wherein the content of the polyglycerol fatty acid ester is not higher than 50% by weight based on total weight of the composition minus a weight of coenzyme Q₁₀. The composition of the present invention can simultaneously provide the good stability of reduced coenzyme Q₁₀ and the high-level absorbability in the living body thereof. The addition of the polyglycerol fatty acid ester especially enhances absorbability of reduced coenzyme Q₁₀ in the living body and hardly inhibits the reduced coenzyme Q₁₀-stabilizing effect of the fat and oil and/or polyol.

The present inventors found the following as described on page 5, lines 14-24 in the specification. While the addition of Tween and Span species (surfactants (emulsifiers)) in wide use markedly decreases the above-mentioned reduced coenzyme Q₁₀—stabilizing effect of fat and oil and/or polyol, the addition of polyglycerol fatty acid esters surprisingly has little influence on the stabilizing effect of at and oil and/or polyol. The Examiner mentions “The applicant’s argument regarding the use of surfactants and associated effects on the stability of claimed composition is not found to be persuasive, because claim 40 is directed to such composition that requires said surfactants/emulsifiers”. However, the composition of claim 40 further comprises an ascorbic acid. The following is shown on page 25, line 33 – page 26, line 6 in the specification. When ascorbic acids are added, the inhibitory effect of the coexistence of a Tween or Span species on the stabilization of reduced coenzyme Q₁₀ is lessened, even upon further addition of a Tween or Span species as a surfactant (emulsifier) other than polyglycerol fatty acid esters. Thus, in claim 40, the effect by the addition of the polyglycerol fatty acid ester does not change, and the polyglycerol fatty acid ester hardly inhibits the reduced coenzyme Q₁₀—stabilizing effect of fat and oil and/or polyol.

On the other hand, Chopra (WO 01/52822 A1) relates to a composition comprising ubiquinol and an amount of a reducing agent effective to reduce or eliminate the oxidation of said ubiquinol to ubiquinone, that composition further comprising an amount of a surfactant or vegetable oil or mixtures thereof and optionally, a solvent effective to solubilize said ubiquinol and said reducing agent. As the Examiner recognizes, Chopra does not disclose the reduced coenzyme Q₁₀-containing composition comprising the polyglycerol fatty acid ester of the present invention.

Motoyama et al. relates to a pharmaceutical composition which provides a high degree of bioavailability of cyclandelate when administered orally. The composition consists of a mixture of (a) a polyglycerol ester of an unsaturated fatty acid or mixtures thereof and (b) cyclandelate. Motoyama et al. only describes coenzyme Q₁₀ (ubidecarenone: oxidized coenzyme Q₁₀) on column 2, lines 55-56 and does not describe reduced coenzyme Q₁₀. Thus, since Motoyama et al. uses oxidized

coenzyme Q10, already oxidized, it does not even suggest the stability of reduced coenzyme Q10. Moreover, Motoyama et al. only describes that the polyglycerol ester of an unsaturated fatty acid is used in order to facilitate the absorptivity of the drug. Furthermore, in Motoyama et al's Examples, there are no examples using a fat and oil together with the polyglycerol ester, and there is only one Example using a solvent together with the polyglycerol ester. All other Examples are for compositions consisting of the drug and the polyglycerol ester of an unsaturated fatty acid or for powdered compositions. Plainly, one skilled in the art understands that the subject matter Motoyama et al. is facilitating the absorptivity of the drug, which is very slightly soluble in water, by using the composition mostly comprising the polyglycerol ester of an unsaturated fatty acid. In addition, though reduced coenzyme Q₁₀ is stabilized in the presence of a fat and oil and/or a polyol and the addition of the polyglycerol fatty acid ester hardly inhibits the reduced coenzyme Q₁₀-stabilizing effect of the fat and oil and/or polyol in the present invention, Motoyama et al. neither discloses nor suggest the effects of the present invention.

It should thus be seen that neither Chopra nor Motoyama et al. disclose nor suggest that the composition can simultaneously have the good stability of reduced coenzyme Q₁₀ and the high-level absorbability in the living body thereof by the constitution of the present invention. Accordingly, the present invention would not have been thought of by one skilled in the art from the combination of Chopra and Motoyama et al., except from the teachings of the present application. Therefore, the present invention logically cannot be seen as obvious.

Finally, with respect to obviousness-type double patenting, by the above amendments the claim 29 of the present invention is not generic to the claim 16 of co-pending application 11/586,511. Therefore, the obviousness-type, double patenting rejection should also be withdrawn.

Respectfully submitted,

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